

Fig 1

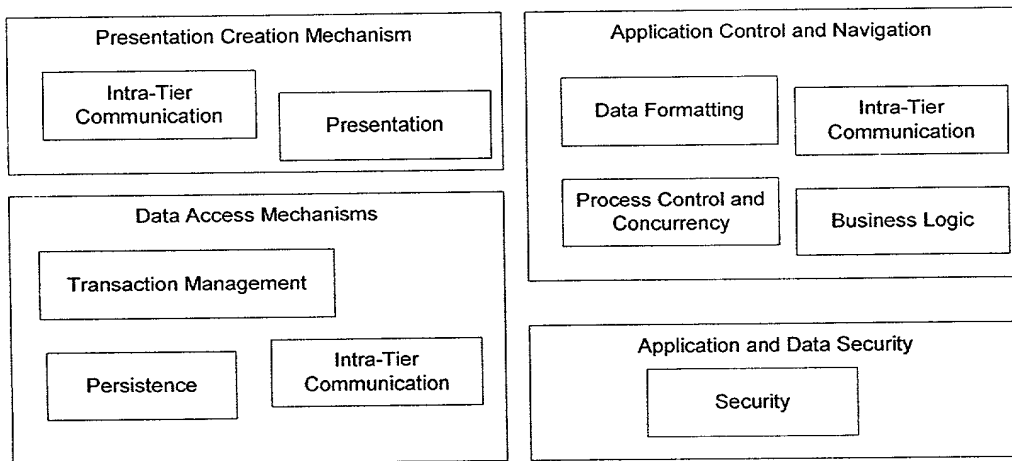


Fig 2

2025-04-20 10:00:00

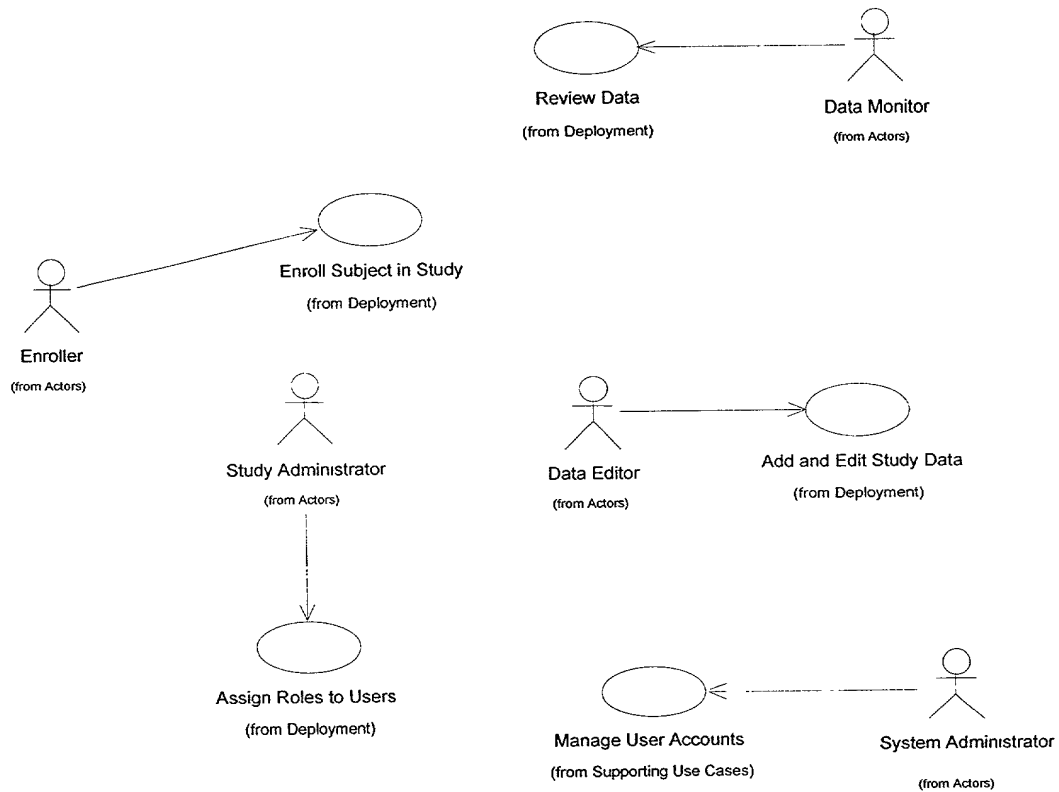


Fig 3

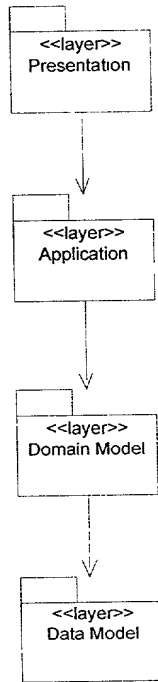


Fig 4

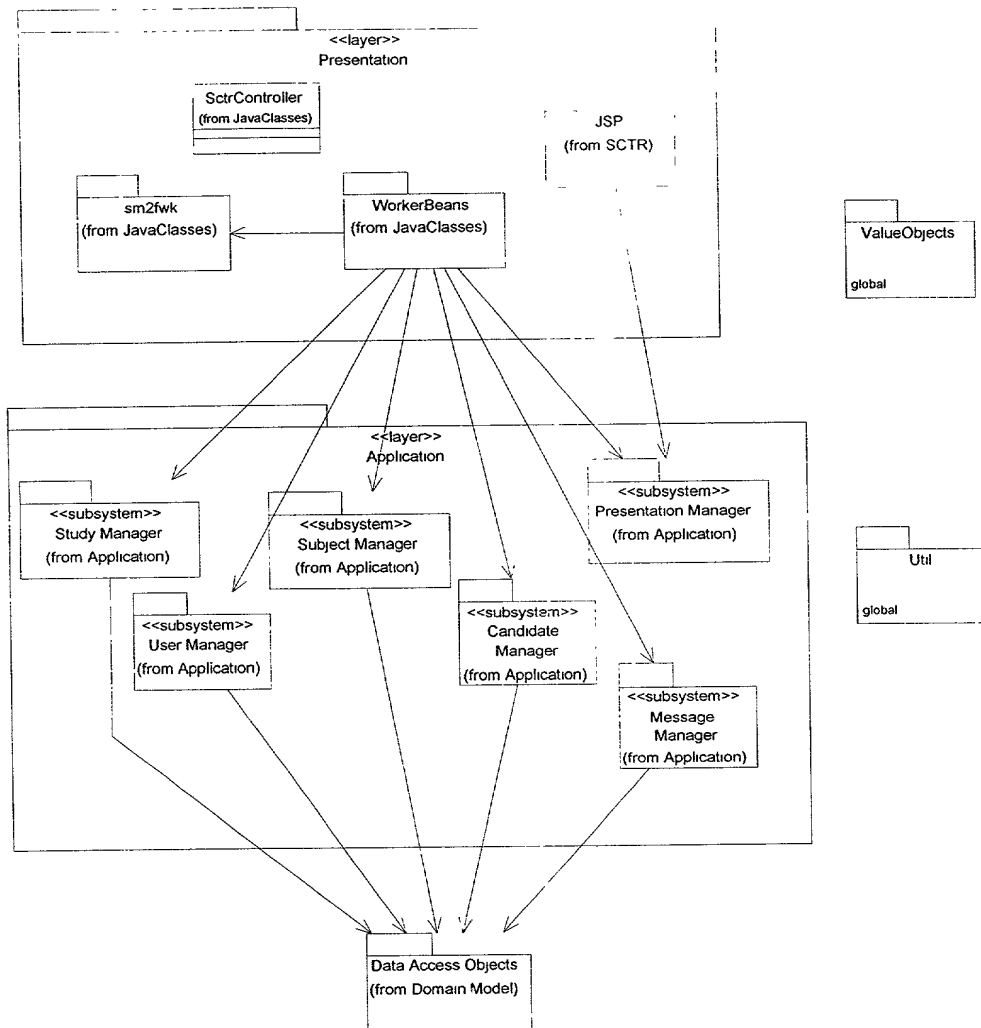


Fig 5

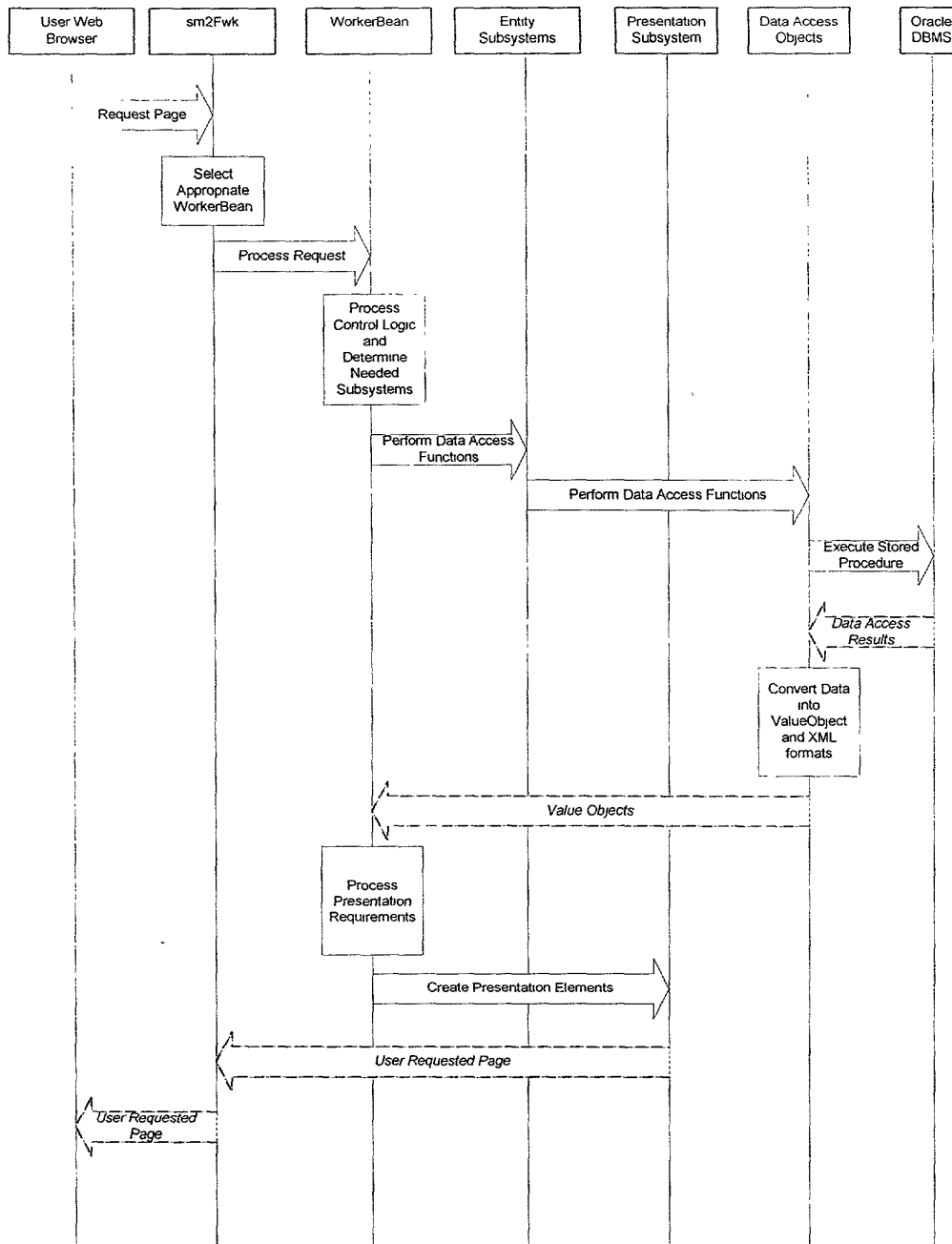


Fig 6

Login Function

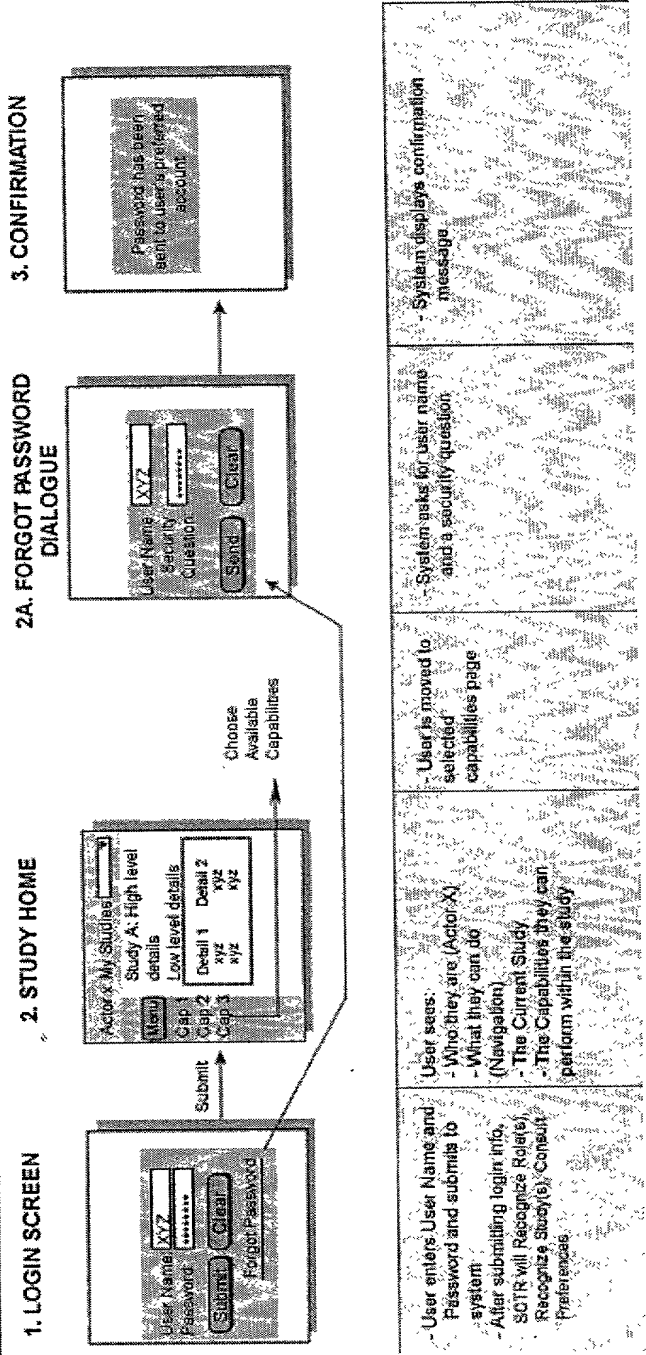



Fig 7


 SPONSORED BY THE
ALBERTO VILAR CENTER

User: Robert Hotchkiss, MD

SCTR Mail | Preferences | Help | Logout

Search: Last Name

[Study Home](#)
[Manage Subjects](#)
[Reports](#)
[Administration](#)
[Register](#)

Study: 445599 Basal Joint Arthritis

Study Home

[Change Studies](#)
[View All Studies](#)

Sponsored by the
Alberto Vilar Center
for Research at the
Hospital for Special Surgery

Problems?
SCTR Administrator
John Doe

[Legal Notices](#)

Summary

PI: Robert Hotchkiss, MD
Collaborators: 6
Enrolled Subjects: 133
Disenrolled Subjects: 10
Status: ACTIVE
Start Date: 09/24/2001
Last Modified: 09/25/2001

Study Alerts

08/12/2001 Subject 123442 Disenrolled from Study
07/23/2001 Collaborator Walker Reed Data Set Editability Suspended
06/18/2001 Enrollment for Basal Joint Arthritis closed
05/13/2001 Enrollment Opened For Fracture Callus Study
05/05/2001 Subject 234558 Enrolled into Basal Joint Arthritis Study

Reference Study Material

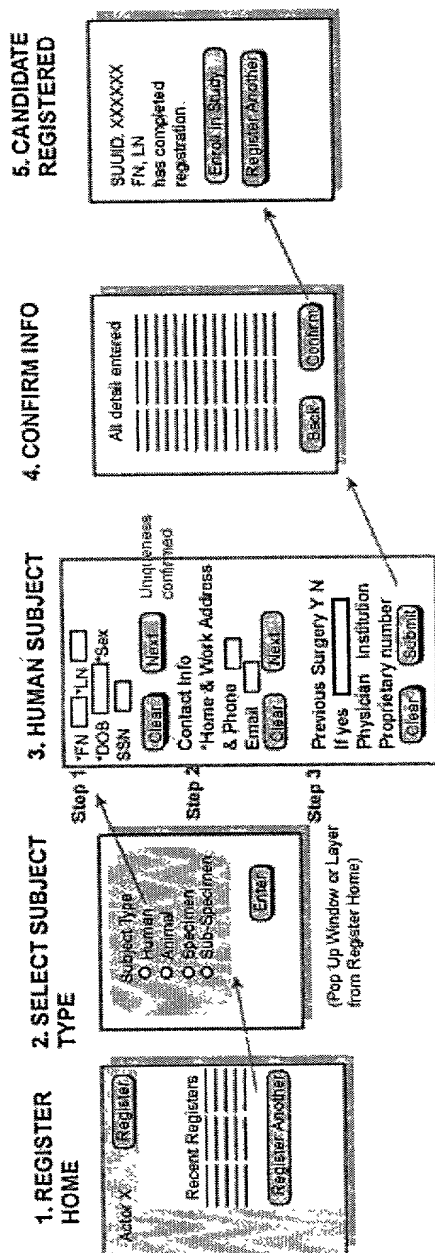
The files below represent background material for the study or points of information that may prove useful to the collaboration effort.

Author	Title	Collected	Modified	Action
Robert Hotchkiss, MD	NIH Grant Application	File Upload	10/01/2001	
Tim Wright, MD	IRB Submission	File Upload	10/01/2001	
Robert Hotchkiss, MD	IRB Consent Form	File Upload	10/01/2001	
Robert Hotchkiss, MD	Surgical Technique Movie	Generic URL	10/01/2001	

[Append Reference Study Material](#)

Fig 8

Register candidate Subject Function



<ul style="list-style-type: none">- Register function is selected- Always available to those with the capability	<ul style="list-style-type: none">- Pick subject type and click enter	<ul style="list-style-type: none">- This is a wizard like process- Step 1 is basic info that leads to uniqueness confirmation- All required fields will be marked- Specimen or Sub-Specimen see Register Candidate Specimen	<ul style="list-style-type: none">- If entry is unique, all detail is presented for confirmation- The user chooses back to change or confirm to register	<ul style="list-style-type: none">- An SUUID is generated and the subject is in the pool- Edit the record- Move on to the next one- Enroll in a study (potentially pre-enroll)
---	---	--	---	---

Fig 9

Register Specimen Function

1. REGISTER HOME 2. SELECT SUBJECT TYPE 3A. SPECIMEN DETAILS 4. CONFIRM INFO 5. SPECIMEN REGISTERED

1. REGISTER HOME

Actor X **Register**

Recent Registers

Register Another

2. SELECT SUBJECT TYPE

Subject Type

☐ Human

☐ Animal

☐ Specimen

☐ Sub-Specimen

Enter

(Pop Up Window or Layer from Register Home)

3A. SPECIMEN DETAILS

Related to subject? y/n

Find

Institution

Physical Location

Received Date

Generation Date

Weight

Clear **Submit**

Search Subject Feature

Uniqueness confirmed

3B. SUB-SPECIMEN FORM

Related to specimen? y/n

Find

Yield

Concentration

Method of Isolation

Clear **Submit**

Search Specimen Feature

Uniqueness confirmed

4. CONFIRM INFO

Related Subject sub id

All detail entered

Back **Confirm**

5. SPECIMEN REGISTERED

Sub ID: XXXXXX is registered

Connected to Sub ID: 123

Enroll in Study **Register Another**

- Register function is selected
- Always available to those with the capability
- Pick subject type and click enter
- All required fields marked *
- "Submit" sends the info for uniqueness checking
- For additional sub-specimen fields look to Rose Domain Model
- Cadaver entry fields include: body location, physical location, age, cause of death, patient history, paired/unpaired, dimensions
- If an entry is determined unique, all detail is presented for confirmation. The user can go back to change or confirm to register
- An Sub ID is generated and the specimen is in the pool
- Ability to edit after acceptance is possible
- Move on to the next one
- Enroll specimens in a study
- Sub-specimens are automatically enrolled as they must be connected to an enrolled specimen

Fig 10

ADVANCED SEARCH

Who I Am
Where I am

Search (Easy, Advanced)

Advanced Search

Keywords

PATIENT

SUID

First Name

Enrollment Date

Profile Created

Last Name

STUDY

Study ID

Study Name

Data sets

Approval Date

Condition

Procedure

Study Type

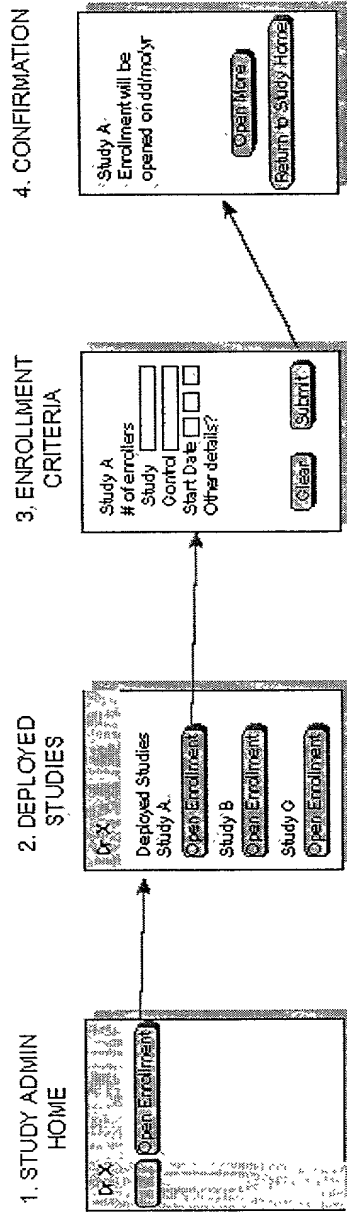
Start Date of Study

Search

Clear

Fig 11

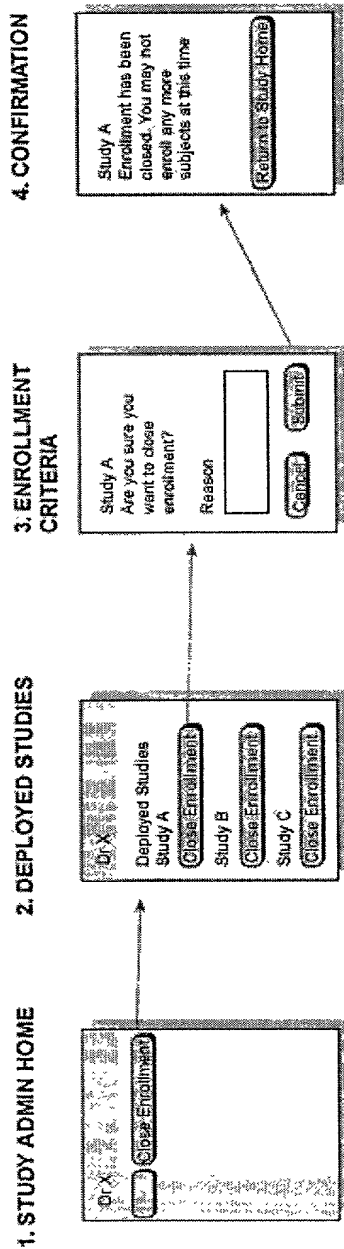
Open Enrolment Functions



- User chooses open enrolment	- User selects study to open enrolment with	- User enters criteria and clicks submit	- Enrolment is opened - Enroller is notified
-------------------------------	---	--	--

Fig 12

Close Enrolment Functions



- User chooses close enrollment	- User selects study to close enrollment with	- System warns user that they are about to close enrollment. - User types in reason for closing enrollment	- Enrollment is closed - Enroller is notified
---------------------------------	---	---	--

Fig 13

Role Definition Function

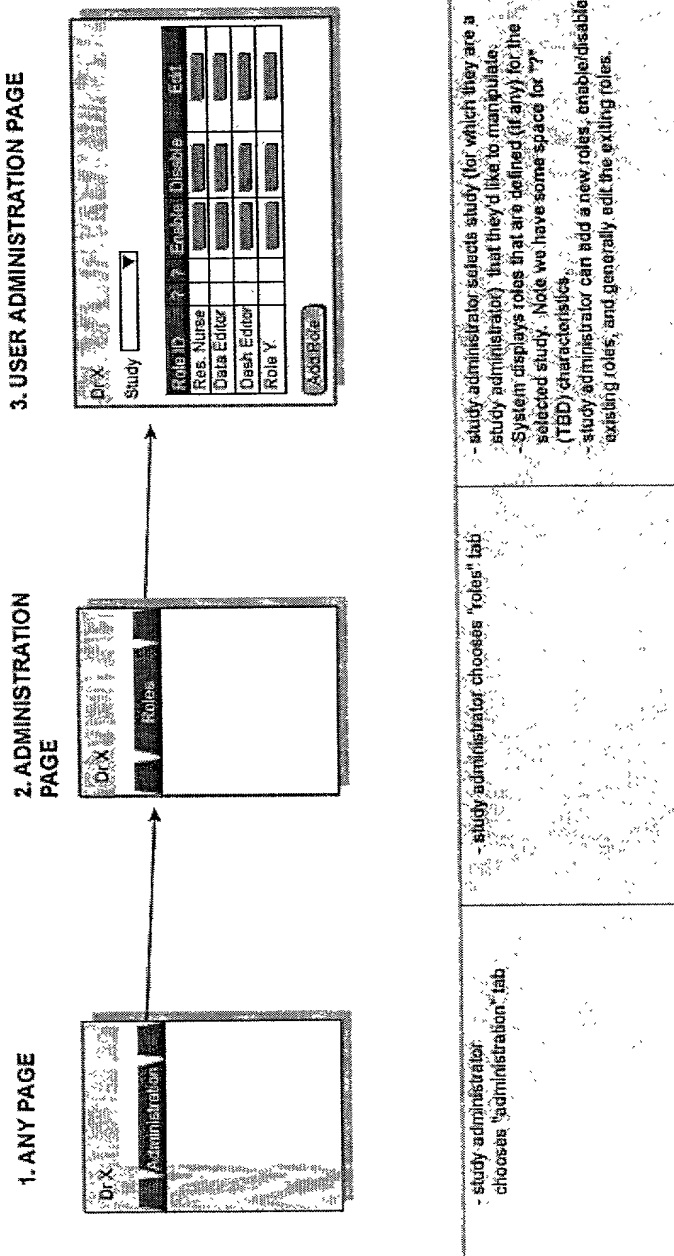


Fig 14a

Role Definition Function (Cont.)

5. CONFIRMATION PAGE

Changes made to study have been committed.

Return to Administration Home

Return to Roles

4. ROLE PAGE

For Study: XYZABC
Role: Research Nurse 3

Capabilities:
Assign Remove

Enroll Subjects:
Assign Remove

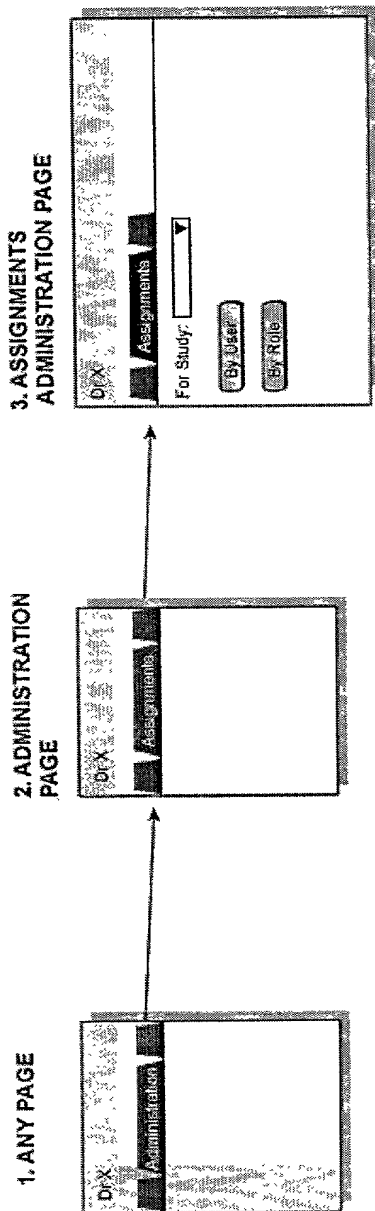
Submit

- study administrator selected Add Role or edit an existing role from previous page or
- when study administrator selects either Assign or Remove, the system refreshes the page to indicate updated information
- the *fault line* simply indicates that there are lots of capabilities and we'll need to find a nice model to reflect them.
- More discrete data-oriented capabilities like Edit Data and Review Data capabilities have a sub-table for known data sets (and the ubiquitous freeform dataset (attachment, link or block of text)).

- System confirms Role revision / creation

Fig 14b

Role Assignment Function



- First the study administrator will specify the study for which they are assigning roles. The choices in the drop down are those for which they are identified as study administrators.
- They can then specify the assign roles "By User" or "By Role" - both forms are presented as a matter of convenience.

- study administrator chooses "assignments" tab

- study administrator chooses "administration" tab

Fig 15a

Role Assignment Function (Cont.)

4A. ROLE ASSIGNMENT BY USER PAGE OR 4B. ROLE ASSIGNMENT BY ROLE PAGE 5. CONFIRMATION PAGE

The diagram illustrates the role assignment process flow. It starts with two alternative pages, 4A and 4B, which lead to a confirmation page 5.

Page 4A: ROLE ASSIGNMENT BY USER PAGE
 - Header: Dr. X
 - Section: Assignments
 - For Study: XYZABC
 - Apply to User: [Dropdown]
 - Assigned Roles: [List]
 - Available Roles: [List]
 - Buttons: Assign, Remove, Submit

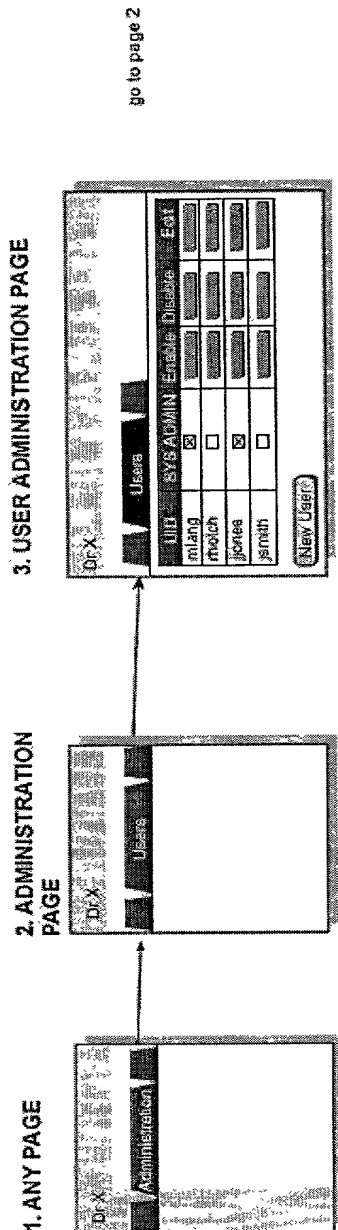
Page 4B: ROLE ASSIGNMENT BY ROLE PAGE
 - Header: Dr. X
 - Section: Assignments
 - For Study: XYZABC
 - Role: [Dropdown]
 - Users With Role: [List]
 - Users Without Role: [List]
 - Buttons: Assign, Remove, Submit

Page 5: CONFIRMATION PAGE
 - Header: Dr. X
 - Message: Changes to roles have been confirmed.
 - Button: Return to Roles

- View if study administrator selected "By User"
 - study administrator can Assign/Remove roles by clicking on the "Assign" and "Remove" buttons
 - System will refresh page when user Assigns / Removes Roles
- View if study administrator selected "By Role"
 - As study administrator can assign/Remove roles by clicking on the "Assign" and "Remove" buttons (assigning users to the roles)
 - System will refresh page when user Assigns / Removes Roles
- System confirms Role assignments.

Fig 15b

User Administration Function



- User chooses "administration" tab
- User chooses "users" tab
- System displays users
- User can:
 - + add a new user,
 - + enable / disable users
 - + edit a user. (choosing edit will take the administrator to the next page)

Fig 16a

User Administration Function (Cont.)

4. USER PROFILE PAGE

DX

UID: First Name: Last Name: Email:	Contact Data: _____ _____ _____ _____
Is System Admin: <input checked="" type="checkbox"/> Is Registrar: <input type="checkbox"/>	Is Study Admin: <input checked="" type="checkbox"/> Studies: Study1 Study2 Study3
<input type="button" value="Submit"/>	

5. CONFIRMATION PAGE

DX

Changes to UID Smith have been committed.

<input type="button" value="Return to Administration Home"/>	<input type="button" value="Return to User Page"/>
--	--

- User creates various aspects of the user's profile.
- Users click submit to commit changes

- System confirms the commit of changes to the user.

Fig 16b

Subject Enrollment Function

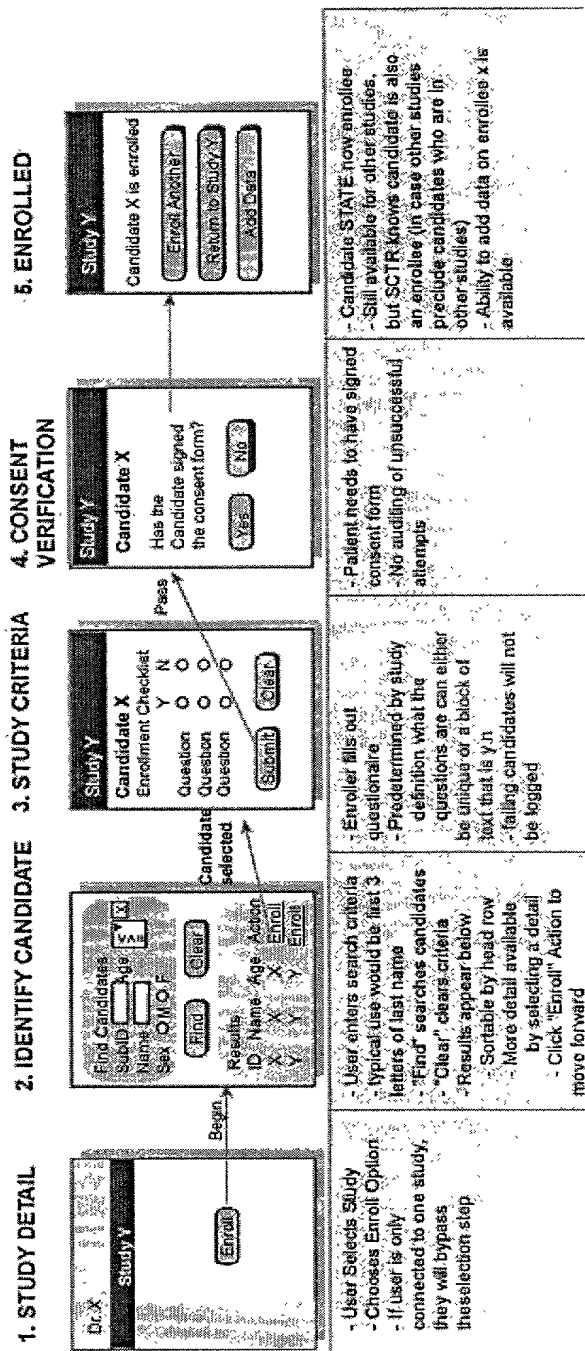


Fig 17

Add/Edit Study Data Functions

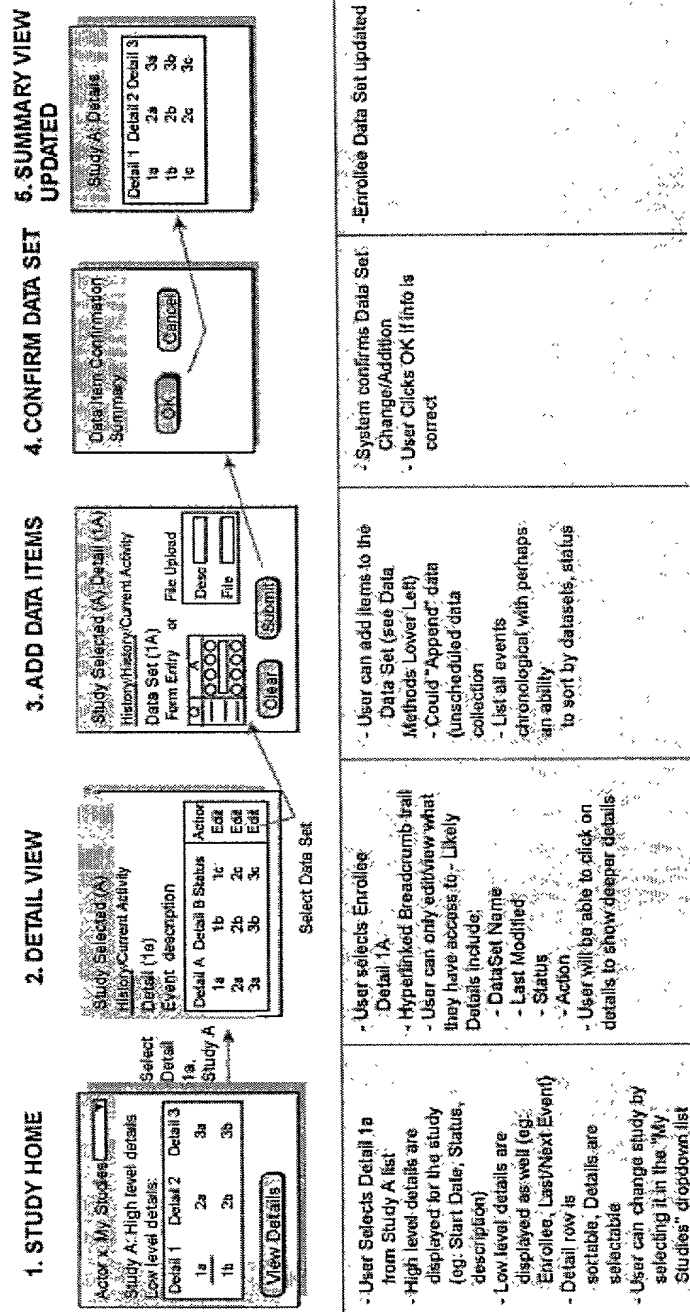


Fig 18

Add/Edit Genetics Data Functions

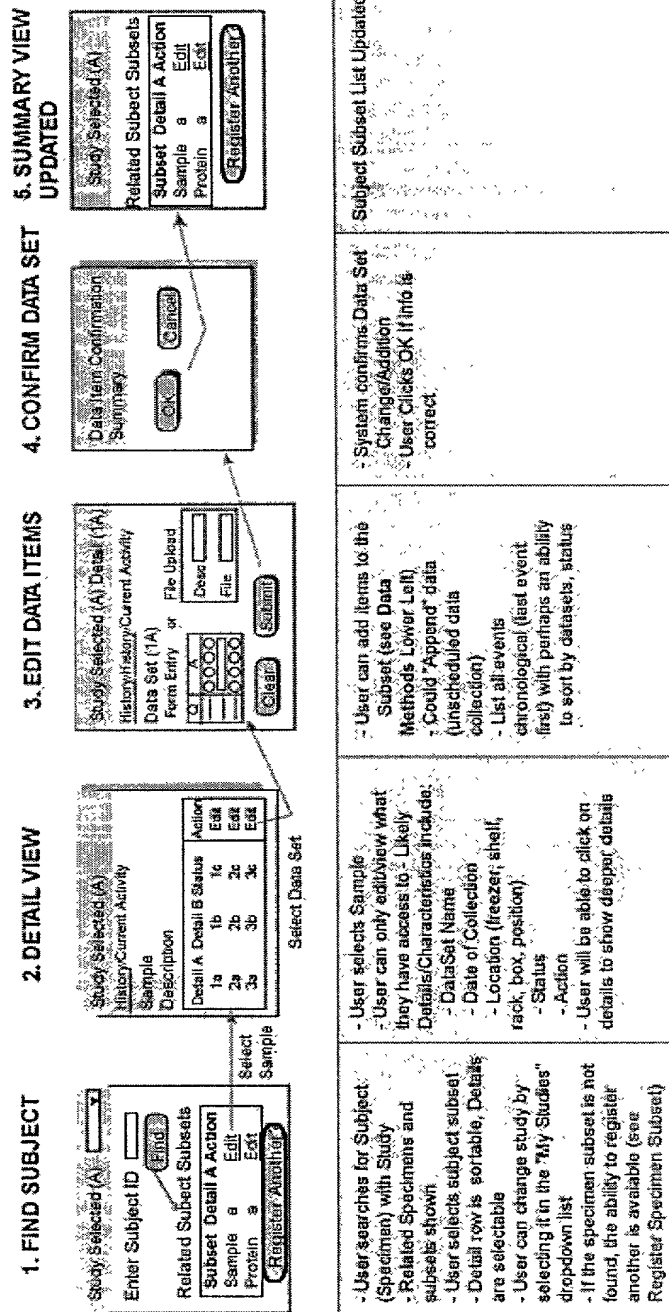


Fig 19

Review Data Functions

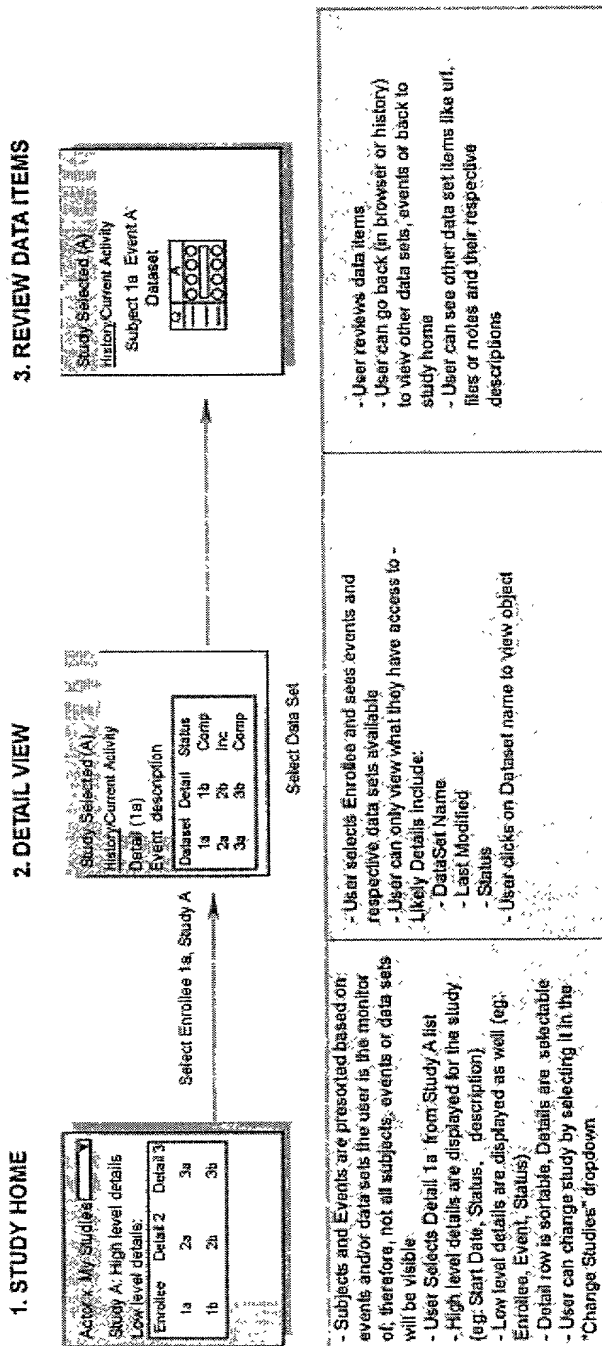


Fig 20

Approve Data Set Functions

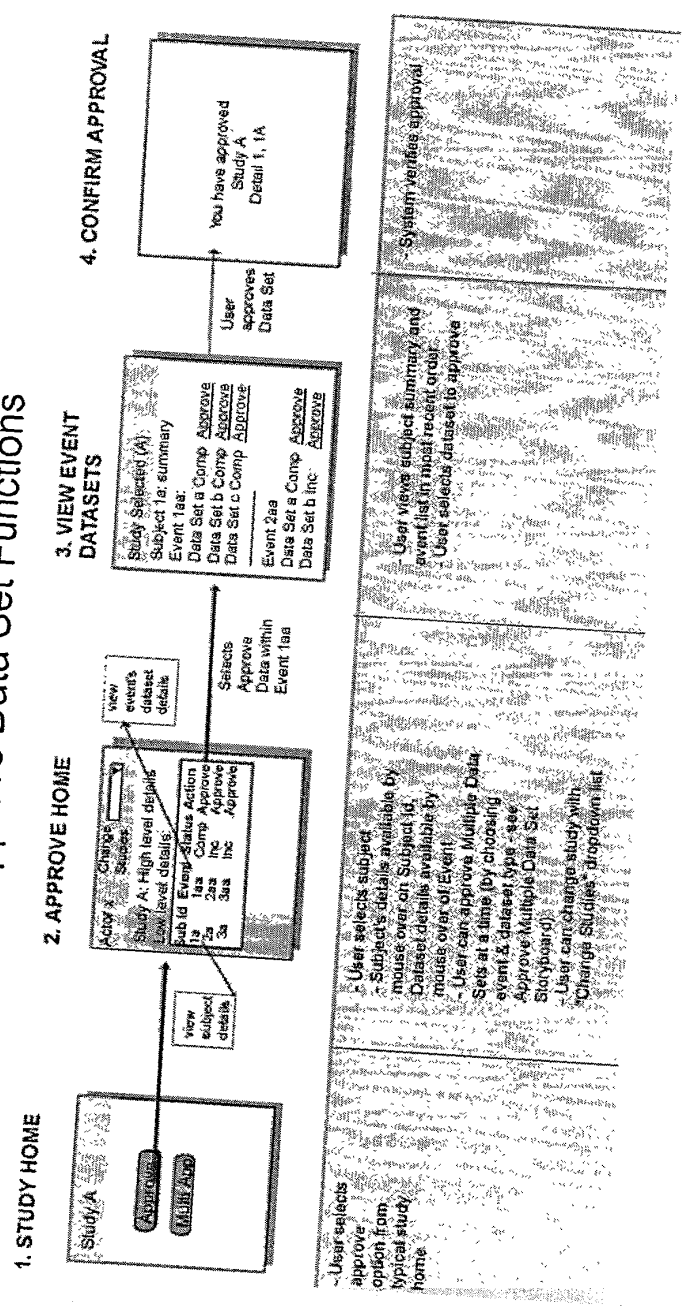


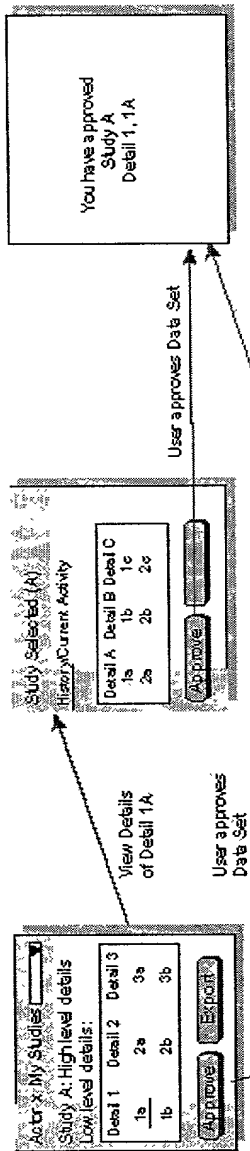
Fig 21

Approve (freeze) Data Set Functions

3. CONFIRM APPROVAL

2. VIEW DETAILS

1. TAILORED HOME PAGE



- System verifies approval

- User can view details of a Subject
- User can approve data from this page

- User sees current study and the subjects enrolled in that study
- User can approve Data Set from this page
- User can approve Multiple Data Sets at a time
- User can change study by selecting it in the "My Studies" dropdown list
- User can export data for analysis in an external tool

Fig 22

Reinstate Function

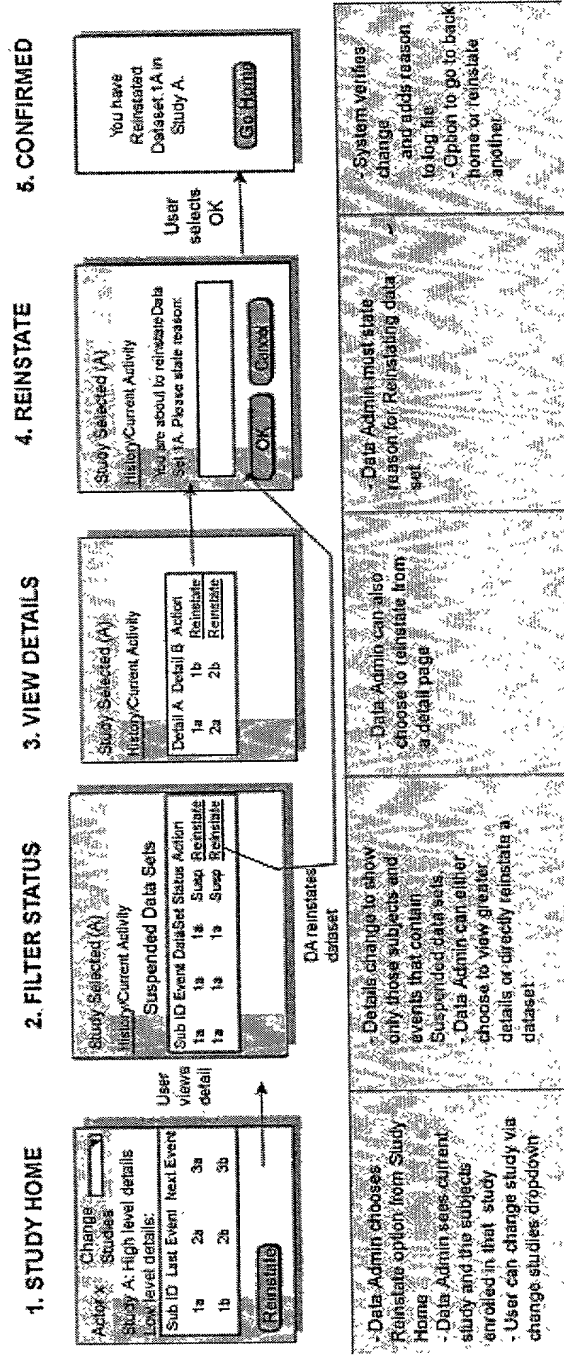


Fig 23

Back To

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Alberto Vilar Center
for Research at the
Hospital for Special Surgery

Problems?
SCTR Administrator
John Doe

[Legal Notices](#)

SCTR Mail Message Center

SCTR Mail Home

Post Message

For:

Study:

Priority:

Title:

Message:

View Messages

To sort alerts, click on the column header that you wish to sort on.

Study: <input type="button" value="Basal Joint Arthritis"/>		
Date	User	Title
09/30/2001	rhochkiss	Enrollment for Basal Joint Arthritis Closed
09/11/2001	twright	Subject 457342 is disenrolled for study
07/23/2001	ariola	Subject 123442 is disenrolled for study
08/12/2001	rhochkiss	Collaborator Walter Reed data Set Editability Suspended
06/18/2001	rhochkiss	Subject 123442 is disenrolled for study
09/23/2001	twright	Enrollment Closed for Basal Joint Arthritis Study
09/11/2001	ariola	Subject 123442 is enrolled into study
07/23/2001	rhochkiss	Collaborator TIGR data set editability has been Reinstated

Fig 24

Back To
-- Select a Study --

SCTR Mail Message Center

SCTR Mail Home

Post Message

For: Priority:

Study:

Title:

View Message

Date: 09/30/2001
From: rhotchkiss
Priority: High
Title: Enrollment for Basal Joint Arthritis Closed
Message:
Enrollment for the Basal Joint Arthritis Study #445599 has been closed as of 12:30pm 09/20/2001. The maximum number of subjects have been enrolled - we have no further need for subjects at this time.

08/12/2001	rhotchkiss	Collaborator Walter Reed data set Editability Suspended	Normal
06/18/2001	rhotchkiss	Subject 123442 is disenrolled for study	Alert
09/23/2001	twright	Enrollment Closed for Basal Joint Arthritis Study	Normal
09/11/2001	lanpla	Subject 123442 is enrolled into study	Low
07/23/2001	rhotchkiss	Collaborator TIGR data set editability has been Reinstated	Normal

Fig 25

Study: 443599 Basal Joint Arthritis

Manage Subjects Home

Enrolled Subject View									
Subject ID	First Name	Last Name	Sex	Age	Last Event	Status	Last Event Date	Next Event	
123456	Mary	Smith	F	22	Initial Visit	Comp	09/11/2001	Surgery	
123455	Brenda	Heidelberg	F	32	Initial Visit	Inc	09/11/2001	Surgery	
123454	Helga	Rothchild	F	48	Initial Visit	Inc	09/11/2001	Surgery	
123453	Donna	Donaldson	F	67	Surgery	App	09/19/2001	1-Mon Postop	
123452	Flora	Dorfman	F	79	1-Mon Postop	Inc	09/11/2001	3-Mon Postop	

Total number of enrollees: 27

Scheduled Event Status View									
EVENT	TBE				DATA ENTRY STATUS				
	Incomplete	Complete	Approved		Incomplete	Complete	Approved		
Initial Visit	18	22	5	3					
Surgery	4	5	12	9					
1-Mon Postop	12	12	3	2					
3-Mon Postop	2	3	2	1					
3-Mon Postop	3	0	0	0					
1-Yr Postop	3	0	0	0					
2-Yr Postop	3	0	0	0					

Fig 26

Change Studies

View All Studies

Manage Subjects

Candidates

Find

Enroll

Enrolled

View

Disenroll

Events

Choose

View Scheduled

View Status

Add Unscheduled

Data Sets

Choose

Edit

Approve

Retract Approval

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Problems?

SCTR Administrator John Doe

Legal Notices

Manage Subjects

Study: 445599 Basal Joint Arthritis

Manage Subjects: Subject View

Subject 123456

General Characteristics

Sex: Female

Age: 20

Race: Caucasian

Height: 6'00

Weight: 125

Eye Color: Brown

Personal Id Info

Associated Medical Info

Event List

Scheduled Events

Event

Initial Study Visit

Surgery

1-Mon Postop

3-Mon Postop

3-Mon Postop

1-Yr Postop

2-Yr Postop

Data Status

Inc

Inc

TBE

Comp

Comp

Inc

Comp

Last Modified

04/08/1998

04/10/1998

04/11/1998

04/10/1999

04/10/2000

04/10/2001

Event Last Modified

Event Name

Modified

Physical Exam

04/08/1998

Surgery

04/10/1998

Add Unscheduled Event

Fig 27

Manage Subjects

Study: 445599 Basal Joint Arthritis

Manage Subjects: Add Unscheduled Event

Subject 123456

Add Unscheduled Event

Event Name:

Change Studies

Manage Subjects

Candidates

Find

Enroll

Enrolled

View

Disenroll

Events

Choose

View Scheduled

View Status

Add Unscheduled

Data Sets

Choose

Edit

Approve

Retract Approval

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Hospital for Special Surgery

Problems?
SCTR Administrator
John Doe

Legal Notices

Fig 28

Legal Notices

Study: 445599 Basal Joint Arthritis
Subject ID: 123456

[Return to Subject view](#) [Return to Event View](#)

[Return to Subject view](#)

Fig 29

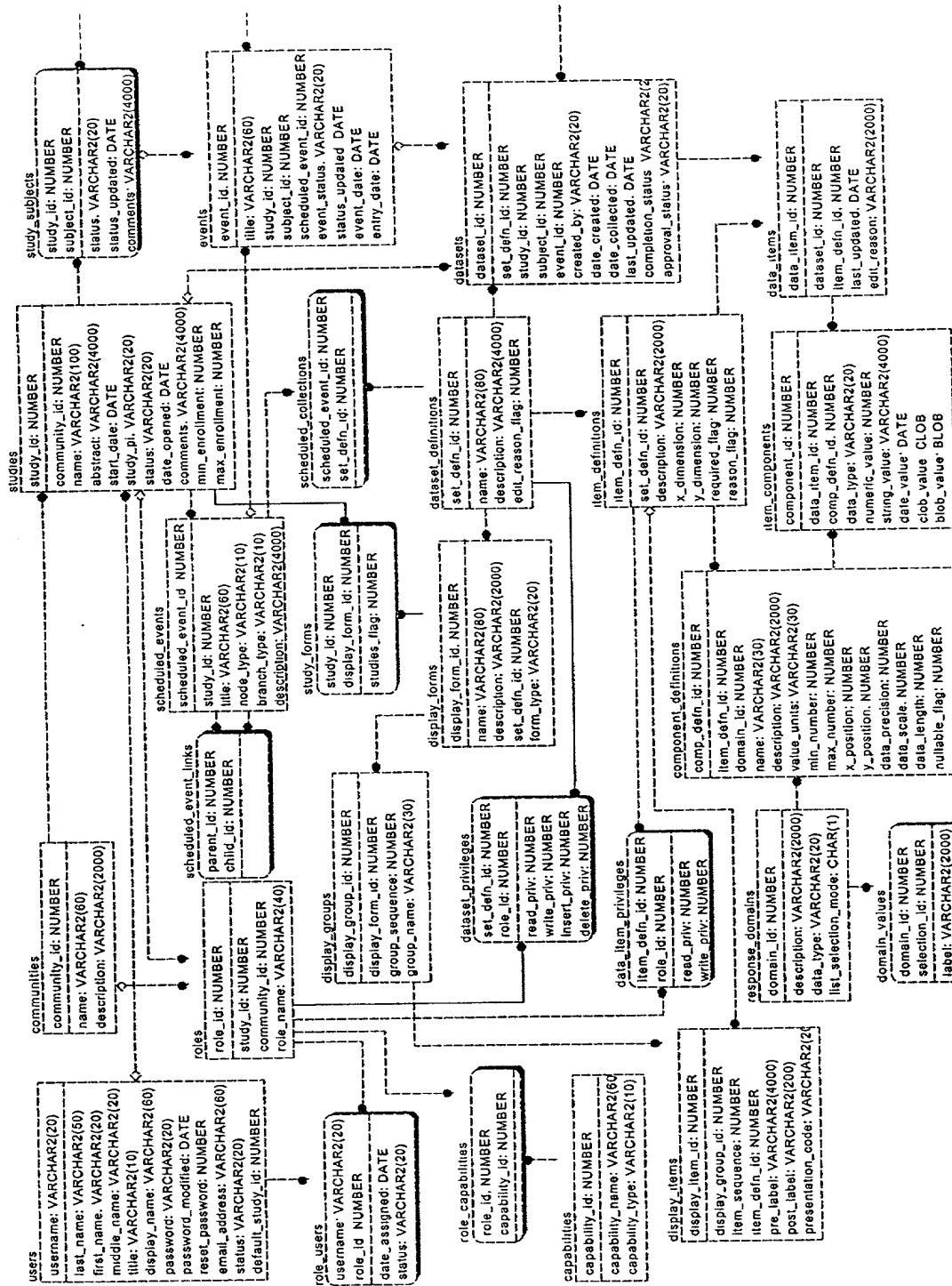


Fig 31a

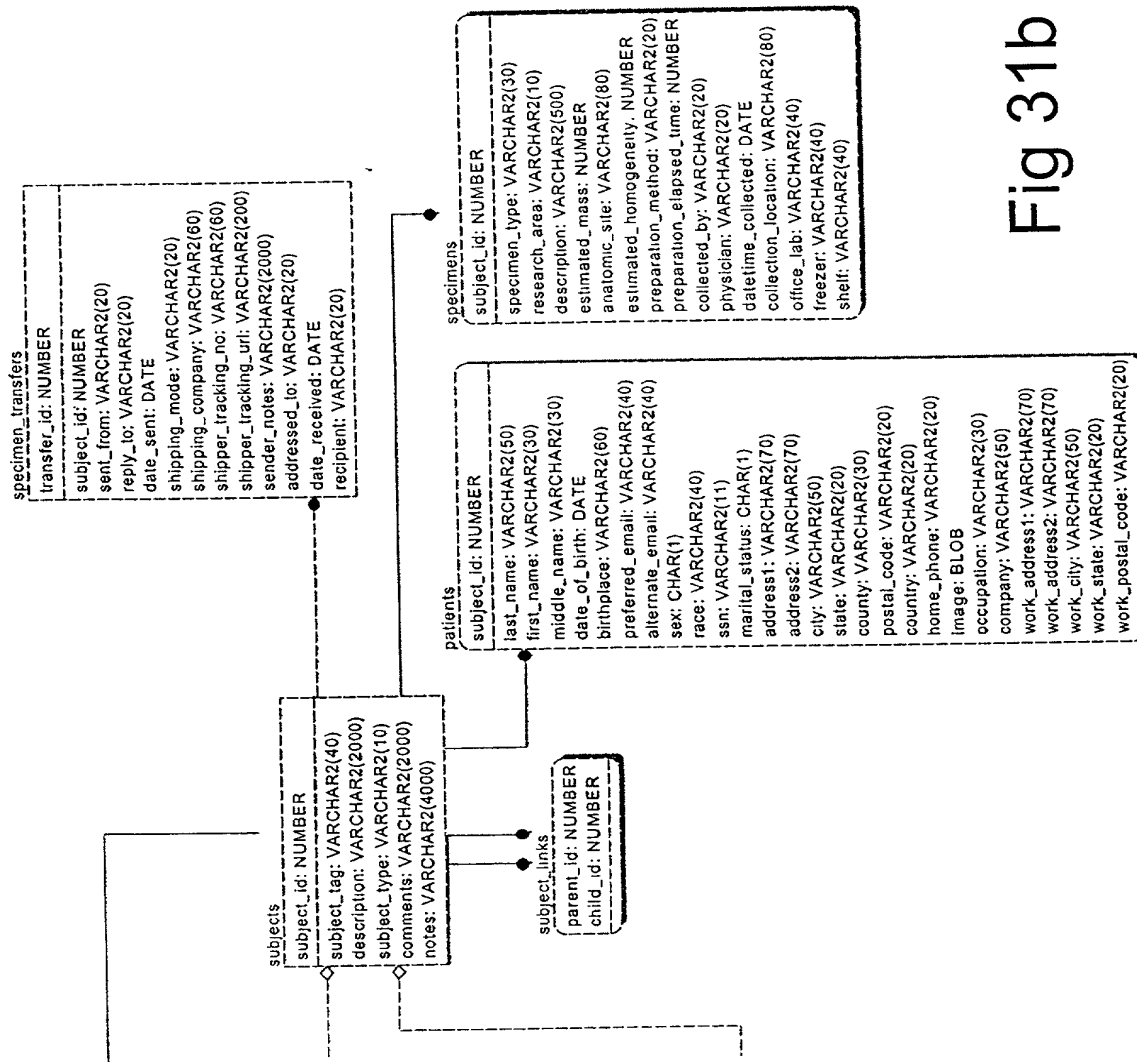


Fig 31b